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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,522	03/23/2004	Elias A. Shaheen	340.182	2749

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THE CLOROX COMPANY
P.O. BOX 24305
OAKLAND, CA 94623-1305

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
07/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patapps@clorox.com

Office Action Summary	Application No.	Applicant(s)	
	10/806,522	SHAHEEN ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGEMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/23/08 wherein claim 25 was amended and claims 26-29 were added.

Note: Claims 1-29 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments and/or amendment filed 4/23/08 to the rejection of claim 25 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive because Applicant amended the claims to overcome the rejections. Therefore, the outstanding rejections are hereby withdrawn.

WITHDRAWN CLAIMS

3. Claims 1-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

NEW GROUNDS OF REJECTION

112 First Paragraph Rejections (New Matter)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims contain new matter because the throughout the specification 'hay fever', not 'fever', is listed as the allergic response. Furthermore, review of any general medical dictionary (e.g., Dox et al, 1993, The Harper Collins Illustrated Medical Dictionary, page 164) discloses that 'hay fever' is defined as a seasonal irritative inflammation of the mucous membranes of the eye and nose caused by an allergic reaction to various pollens. *In addition, Dox et al discloses that hay fever is not actually associated with a rise in body temperature*. However, the term 'fever' is defined as a rise in body temperature above the normal of 98.6 ˚F. Thus, Applicant is respectfully requested to replace 'fever' with 'hay fever' in claims 25-29 to overcome the rejection and in order that the claims may be consistent with the disclosure.

112 Second Paragraph Rejections

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28: A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then

narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the broad recitation mold, and the claim also recites mold spores which is the narrower statement of the range/limitation.

Claims 28 and 29: The claims as written are ambiguous because of the phrase 'using a residue from treatment of the allergen with the composition'. In particular, it is unclear what specific residue(s) Applicant is claiming that is/are compatible with the instant invention. Furthermore, it is noted that since the term 'residue' is defined as matter left after completion of an abstractive chemical or physical process', the species compatible with the instant invention are ambiguous.

103 Rejection

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camper et al (US Patent No. 6,589,568) in view of Rutala et al (Infect. Control Hosp. Epidemiol., 1998, Vol. 19, pages 323-327).

Camper et al disclose a therapeutic mixture containing an alkali metal hypohalite (AMH). The mixture is applied topically and is capable of treating subcutaneous tissue. The preferred AMH is sodium hypochlorite. The AMH penetrates through the skin's pores and lymph nodes into the subcutaneous tissue. The AMH may be used to stimulate the immune system to alleviate and sometimes 'cure' inflammation, aches, pains, and other symptoms caused by microbial (e.g., viral, bacterial, fungal, and parasitic) infection, arthritis, hemorrhoids, and allergies (see entire document,

especially, abstract; column 1, lines 63-67; column 2, lines 21-29; column 3, lines 59-67). Camper et al disclose that treatments disclosed in the art may involve intravenous delivery which while effective may be costly (column 2, lines 1-7). In column 3, lines 27-52, various concentrations of AMH solutions are disclosed. Camper et al disclose that for the skin lotion, the AMH (e.g., sodium hypochlorite) remains in a liquid state for more than 20 minutes which is sufficient time for it to penetrate the pores and lymph nodes of the subject (column 4, lines 1-7). In Example 6, column 5, the mixture of Camper et al is used for dermatitis. In summary, Camper et al fail to disclose that the mixture is administered subcutaneously. In addition, the reference fails to specifically state that it may be used for testing allergic responses in a subject. Also, Camper et al fail to disclose a specific range of composition (the hypohalous acid, hypohalous acid salt, or mixtures thereof). Furthermore, the reference fails to disclose all possible allergens that may be analyzed by their method.

Rutala et al disclose the stability and bactericidal activity of chlorine solutions. The solutions were used to test various bacteria (see entire document, especially, abstract; and page 323, see entire page). In Table 2,page 326, the bactericidal activity of various concentration of hypochlorite solution is disclosed in distilled and tap water. The concentration of the hypochlorite solutions used varied from 1 ppm to 470 ppm.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Camper et al using the teachings of Rutala et al and generate a method of in vivo testing of allergic responses as set forth in independent claims 25-28 for the reasons set forth below. (1) A skilled artisan would be

motivated to administer the hypohalous mixture by subcutaneous injection because Camper et al disclose that intravenous administration is a possible mode of delivery even though effective it may be costly. In addition, Camper et al disclose that while the composition is applied topically, the AMH is delivered to the dermal, epidermal, and to subcutaneous tissue. Furthermore, Camper et al disclose that if the mixture is placed on skin as a lotion, the AMH remains in the liquid state for more than 20 minutes which is sufficient time for it to penetrate the pores and lymph nodes of the subject. Thus, a skilled artisan would recognize that if the mixture remains as a liquid for 20 minutes, injecting the mixture subcutaneously would not only enable one to administer the mixture to a targeted site, but to obtain results from the mixture more readily. (2) While the instant invention is for testing allergic responses, a skilled artisan would be motivated to use the solution of Camper et al to test for allergic response because the document discloses that the AMH stimulates the immune system to alleviate and sometimes 'cure' inflammation, aches, pains, and other symptoms caused by microbial infections and allergies. Thus, since it is known that AMH is capable of performing such actions, a skilled artisan would be motivated to monitor/evaluate/test a subject to ascertain whether or not the AMH is performing in a desired manner. Also, it would have been obvious to one of ordinary skill in the art to broadly test various allergic responses (i.e., sneezing, red eyes, skin rash, fever, runny nose, etc.) and allergens because Camper et al disclose that their invention may be used for various types of ailments including inflammation, skin rashes (dermatitis), colds, and allergies. Hence, the skilled artisan would recognize that such ailments are associated with those known

in the art to result from pollen, mold, pet dander, dust mites, cockroaches and mixtures thereof. (3) It would have been obvious to one of ordinary skill that the mixture in Camper et al is capable of being used with mold spores because Camper et al disclose that their invention may be used with fungal microbes. (4) It would have been obvious to optimize and generate a concentration range of the AMH mixture because Camper et al discloses that depending on the form of the AMH mixture, the concentration of the mixture will vary for the ailments being treated. Furthermore, Rutala et al disclose the stability and bactericidal activity of various chlorine solutions. In Table 2 (page 326) of Rutala et al, various concentrations of a hypochlorite solution ranging from 1 to 470 ppm is disclosed for use with various bacterial. The range of Rutala et al encompasses the range set forth in Applicant's claims. Thus, a skilled artisan would be motivated to optimize the range for the desired allergens based on the teachings of Camper et al and Rutala et al since the general conditions of the claim are disclosed in the prior art. Hence, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 05 USPQ 233).

Since both Camper et al and Rutala et al disclose hypohalite mixtures, the references may be considered to be within the same field of endeavor. Thus, the reference teachings are combinable.

COMMENTS/NOTES

12. It is once again noted that Applicant elected Group III (claim 25 and newly added claims 26-29) without traverse in the reply filed 11/1/07. Thus, Applicant is respectfully requested to cancel the non-elected subject matter.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

July 18, 2008